REMARKS

The present communication is responsive to the official action of March 30, 2004. Claims 34-36 and 39-56 presently appear in this case. Claims 34-36, 39 and 42-49 have been allowed. The remaining claims have been rejected. The official action of March 30, 2004, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for isolating and identifying polypeptides capable of binding to the death domain motif of a regulatory protein containing a death domain. The method involves assaying polypeptides to be tested for binding to the death domain motif of the regulatory protein and then isolating and identifying any polypeptide that binds to that motif. The regulatory protein is NGF-R, MORT-1 or ankyrin 1.

Claims 40, 41 and 50-55 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner states that the claims encompass methods of producing proteins identified by a screening process, and that in order to make such proteins they must first be identified. The

examiner states that, while methods for identification are set forth, no proteins are identified, other than the death domain containing proteins themselves, which appear able to associate with each other. The examiner states that one of skill in the relevant art would not conclude that applicant was in possession of the genus of death domain binding proteins. The examiner states that there is no indication that the methods were actually implemented to identify any binding proteins, and that the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, regardless of the complexity or simplicity of the methods of identification and production. Thus, the examiner states that, since applicant is not in possession of the genus of death domain proteins, applicant is not in possession of methods of producing them. This rejection is respectfully traversed.

The present claims are not directed to proteins or other chemical compounds. The present claims are directed only to process steps. The examiner has conceded that there is written description for the isolating and identifying step. Thus, while no chemical compounds have been identified, the examiner concedes that the process for identifying such proteins does find written

description support in the specification. It is not necessary to know *ab initio* what the sequence of the polypeptide identified is in order to be in possession of a method of producing a polypeptide. Any polypeptide of identified sequence can be produced by means well known to those of ordinary skill in the art. Peptide synthesis, either by synthetic chemistry or by recombinant DNA technology, was extremely well known to one of ordinary skill in the art at the time of filing of the present application.

For example, claim 40 is dependent from claim 34. Claim 34 is drawn to a method of isolating and identifying polypeptides. The first step is assaying polypeptides to be tested. Thus, in order to test a polypeptide, the polypeptide must already be available. As a part of the process, they are isolated and they are further identified. Once a polypeptide is isolated and identified, regardless of its sequence, the method of producing more of it is certainly well within the possession of the inventor.

Claim 41 specifies that the producing step comprises producing the polypeptide by recombinant DNA procedure. Due to the genetic code, once one of ordinary skill in the art has isolated and identified the sequence

of a polypeptide, one is automatically in possession of all possible DNA sequences that encode that polypeptide. Thus, it is a trivial matter for anyone of ordinary skill in the art in recombinant biotechnology to synthesize an appropriate DNA that encodes the polypeptide, and produce it by recombinant DNA procedures. See paragraph 107 of the present specification. This is especially the case when the assaying step is a yeast two-hybrid procedure, as is set forth in claim 36. An example of such a procedure is in Example 3, paragraphs 133-136, of the present specification. Note particularly paragraph 136, where it can be seen that the positive transformants are already present in clones carrying the sequences encoding the newly identified proteins. One does not have to know the sequence of the DNA within that clone in order to culture it and recover the protein produced thereby. New claim 56 has now been added, which is the same as claim 40, but dependent from claim 36.

Accordingly, the present specification does indeed disclose methods by which any given polypeptide identified by the admittedly fully described and enabled identification process can then be produced. One does not need to know *ab initio* what will be the sequence of any polypeptide that will be found in order to understand that

the inventor was in possession of the concept of producing that product once it is found. As the claim does not require that one know the chemical structure of the encompassed genus of polypeptides, this rejection is untenable. Reconsideration and withdrawal thereof is therefore respectfully urged.

Claims 40, 41 and 50-55 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for methods of producing NGF-R, MORT-1, and ankyrin 1, does not reasonably provide enablement for producing death domain binding proteins as broadly claimed. The examiner again states that applicant is not in possession of the proteins identified by the screening method, and as there are no working examples, it is not possible to produce such proteins. The examiner states that an assay for finding a product is not equivalent to a positive recitation of how to make a product, regardless of the ease of screening, and therefore would require undue experimentation to produce the proteins as claimed. This rejection is respectfully traversed.

As discussed above, one need not know what a specific sequence of a given polypeptide is in order for the production of that given peptide to be within the

skill of the art. The independent claims that have been allowed require isolation and identification of a polypeptide. Once that polypeptide is identified, it is a trivial matter to synthesize it. One does not need to be aware of different methods of synthesis for every different amino acid sequence. Any amino acid sequence can be synthesized. Any amino acid sequence can also be readily produced by recombinant DNA procedures. It would not take undue experimentation to figure out how to synthesize a given identified polypeptide.

The present claims are not directed to a genus of polypeptides. The present claims are drawn only to a method of identifying and producing a polypeptide. Once the polypeptide is identified, which the examiner conceded is supported by enabling disclosure, then the production of that polypeptide does not require undue experimentation, regardless of the sequence thereof. This is particularly the case with respect to the yeast two-hybrid method disclosed, for example, in Example 3 of the present specification, in which the clones encoding the positive polypeptides are already in hand as a result of the procedure used. The present claims are not claiming unknown polypeptides or proteins. The present claims are not impossible to search, and indeed may be readily

searched. The first step of the claim requires identifying a polypeptide. This is admittedly enabled. The examiner has not explained why the production of any given identified polypeptide would require undue experimentation, or would not be within the skill of one of ordinary skill in the art in the time frame of 1995. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

It is submitted that all the claims now present in this case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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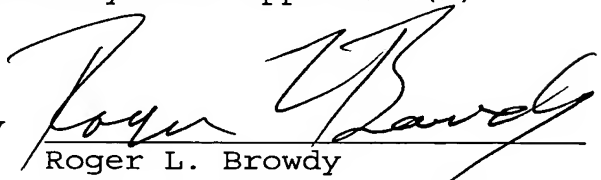
By 
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